Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of an intervention program based on the family-centered model on the level of health literacy, understanding of the disease and the quality of life of family caregivers of the elderly with type 2 diabetes

Protocol summary

Study aim

Determining the effect of an intervention program based on the Coop Care Model on resilience, health literacy level, understanding of the disease, and quality of life of family caregivers of elderly people with type 2 diabetes

Design

A single-blind, randomized, controlled clinical trial on 90 caregivers of elderly people with type 2 diabetes. The card methodis used for randomization.

Settings and conduct

1- The study will be conducted in health centers in Shahrekord city. 2- The study will be conducted on 90 caregivers of elderly people with type 2 diabetes. 3- Blinding is done on patients and their clinical caregivers, in such a way that until the end of the study, only the project administrator was aware of the caregiver groups, and the caregivers and patients themselves were not aware of their group type at all.

Participants/Inclusion and exclusion criteria

1- Willingness to participate in the study 2- Caregiver age over 18 years and under 65 years 3- Not caring for members of the health team 4- Ability to read and write in Persian 5- Self-declared that he/she does not have a known psychiatric disorder 6- The person is designated as the primary caregiver by the patient 7- The patient under the care of the elderly has type 2 diabetes

Intervention groups

Intervention group: In this study, a six-session program is carried out over a period of one month. These sessions are conducted in nine groups of five people, with two sessions in Shahrekord city health centers for 60 minutes and four sessions in the form of telephone calls for 30 minutes, along with follow-ups through WhatsApp groups over a period of one month by the researcher. Control group: no intervention was performed in this group.

Main outcome variables

Resilience, health literacy level, understanding of illness, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181122041720N4**
Registration date: **2025-03-27, 1404/01/07**
Registration timing: **prospective**

Last update: **2025-03-27, 1404/01/07**
Update count: **0**

Registration date

2025-03-27, 1404/01/07

Registrant information

Name

Shirin Madadkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3338 2382

Email address

shirinmadadkar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-08-21, 1404/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of an intervention program based on the family-centered model on the level of health literacy, understanding of the disease and the quality of life of family caregivers of the elderly with type 2 diabetes

Public title
The impact of the Coop care model on family caregivers of elderly diabetics

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willing to participate in research. Be careful not to be a member of the health team Must be able to read and write in Persian. Do not simultaneously care for someone with another chronic illness. A person is designated by the patient as the primary caregiver. The patient under elderly care has type 2 diabetes. The caregiver must be over 18 years of age and under 65 years of age. Self-declares that he/she does not have a known psychiatric disorder

Exclusion criteria:
Participate in a similar training program

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Ninty caregivers of patients with type 2 diabetes who were eligible for the study are randomly assigned (by card method) to the experimental and control groups, so that 45 cards with number one and 45 cards Number two will be placed in a package in an envelope. And on the day of random division of research units, caregivers will be asked to choose a card. People who belong to number one are in the test group. And the people assigned to number two will be in the control group

Blinding (investigator's opinion)
Single blinded

Blinding description
The people in the intervention and control groups are not introduced to each other at all before, during, and after the intervention, and they do not meet each other until the end of the study, so they do not know which group the caregiver is in. Rather, the project administrator is only informed of which caregivers are in which group until the end of the study. Only people in the intervention group will be given the necessary supplementary materials and the necessary arrangements for holding the meetings in the WhatsApp groups, while these materials and arrangements will not be informed to the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University, Shahrekord Branch

Street address
Islamic Azad University, Shahrekord Branch

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8813733395

Approval date
2025-03-17, 1403/12/27

Ethics committee reference number
IR.IAU.SHK.REC.1403.402

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Resilience

Timepoint
Before the intervention, after the intervention and three months after the intervention

Method of measurement
Connor and Davidson Resilience Questionnaire (CD-RISC)

2

Description
Health literacy

Timepoint
Before the intervention, after the intervention and three

months after the intervention

Method of measurement

TOFLA Health Literacy Questionnaire (TOFHLA)

3

Description

Illness Perception (IPQ-R)

Timepoint

Before the intervention, after the intervention and three months after the intervention

Method of measurement

Illness Perception Questionnaire (IPQ-R)

4

Description

Minnesota Quality of Life

Timepoint

Before the intervention, after the intervention and three months after the intervention

Method of measurement

Minnesota Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Caregivers in the intervention group will participate in 6 training sessions designed based on the COOP model (reference). These sessions will be conducted by the researcher in nine groups of five people, with two sessions in the health centers of Shahrekord for 60 minutes and four sessions in the form of telephone calls for 30 minutes, along with follow-ups through WhatsApp groups over a period of one month. The scheduling of these sessions will be done in agreement with the researcher and the caregivers. In these sessions, the three main problems of each caregiver in relation to patient care, such as the patient's activity level, strategies for improving resilience, and other issues, will be examined based on the COOP model. In-person sessions, lecture techniques, question and answer, educational images, and educational booklets will be used according to the needs of the patients' caregivers.

Category

Other

2

Description

Control group: Control group: In the control group, caregivers were provided with the necessary care and training, and no intervention was performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord County Health Center

Full name of responsible person

Shirin Madadkar Dahkordi

Street address

Shahrekord, Shahid Bahonar Street - Next to Imam Khomeini's (RA) Prayer Room

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshid Kheiri

Street address

Shahrekord - Rahmatieh - Islamic Azad University

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Email

shahrekord@iauece.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Shirin Madadkar Dehkordi

Position
Faculty

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available